Particulate Matter NAAQS

Risk Analysis Project Plan

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DRAFT

February 13, 1996

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I. Introduction

The Particulate Matter (PM) National Ambient Air Quality Standard (NAAQS) Development Project Plan, presented to the Clean Air Scientific Advisory Committee (CASAC) in December 1994, included proposed risk analyses that would assess the effects of alternative PM standards on reducing estimated health risks attributable to PM. Over the past several months, while the assessment of the health effects literature upon which such risk analyses would be based was being clarified through review and revision of the PM Criteria Document, OAQPS has been conducting a scoping study on how such risk analyses might be conducted. The methodology, however, was not ready for inclusion in the draft Office of Air Quality Planning and Standards (OAQPS) Staff Paper reviewed by CASAC in December 1995. In their letter of January 5, 1996 to the Administrator commenting on the revised draft PM Criteria Document and the draft OAQPS Staff Paper, CASAC expressed the view that a risk analysis is an important element in making regulatory decisions on the PM NAAQS. Further, the CASAC recommended that the Staff Paper be revised to include "tables showing the expected reductions in mortality and morbidity that would occur if the present PM-10 standards were revised to include PM-2.5 standards within the proposed ranges" presented in the draft OAQPS PM Staff Paper.

In response to the CASAC recommendations, this PM NAAQS Risk Analysis Project Plan is designed to outline proposed approaches and highlight key issues concerning analyses to estimate the health risk posed by PM under existing air quality levels in selected example cities ("as is" health risk) and upon attainment of various alternative standards. This plan is intended to facilitate CASAC review and advice on the proposed approaches and key issues in advance of the completion of such analyses and presentation of results in the next draft of the OAQPS Staff Paper.

II. Framework for Health Risk Analysis

A. Overview

The primary purpose of the PM health risk analysis project is to provide quantitative estimates of the risk to public health associated with existing air quality levels and with air quality levels that would occur upon attainment of the current PM-10 and alternative PM-2.5 standards. As part of such analyses, explicit and, where possible, quantitative characterizations of the uncertainties in the resulting risk estimates will be developed, as well as information on background incidence rates for the health effects endpoints considered in the analyses. It is anticipated that this analysis will be most useful in evaluating alternative levels of standards, rather than in selecting the most appropriate indicator. Such information is intended to assist the Administrator in selecting primary PM standards that will protect the public health with an adequate margin of safety, recognizing that such standards will not be risk-free. The proposed risk analyses focus on selected health effects endpoints such as increased daily mortality, increased

hospital admissions for respiratory causes, and increased respiratory symptoms for children. Although the risk analyses will not address all of the various health effects endpoints for which there is some evidence of association with exposure to PM, all such effects are identified and considered in the OAQPS Staff Paper.

The proposed PM health risk analysis is similar in many respects to the health risk analysis recently conducted as part of the ozone NAAQS review (OAQPS Ozone NAAQS Staff Paper, 1995, and Whitfield et al., 1995), which was favorably reviewed by CASAC in its closure letter to the Administrator on the Ozone NAAQS Staff Paper. Both the ozone and proposed PM analyses:

- estimate risks for a number of example cities, rather than attempt a nationwide analysis;
- analyze risks under a recent year of air quality (labeled "as is") and under a situation where air quality just attains various alternative standards under consideration; and
- estimate risks only for concentrations exceeding an estimated background level.

While the ozone risk assessment required human exposure estimates as an input for some of the health endpoints examined, due to the use of exposure-response functions from human clinical studies, the PM risk assessment is focused on health endpoints for which only functions from human epidemiological studies are being used. Since these studies rely on fixed-site, population-oriented monitors and provide concentration-response functions, no human exposure analysis inputs are required to conduct the PM risk analysis. The approach taken in the proposed PM risk analysis is very similar to that used for the increased hospital admission endpoint in the ozone risk assessment, which also relied on a human epidemiology study for this health effect category.

The PM health risk model combines information about PM air quality for a specific city with concentration-response functions derived from various epidemiological studies and baseline health incidence data for specific health endpoints to derive estimates of the number of effects that would occur per year under "as is" air quality or upon just attaining the current PM-10 standards and alternative PM-2.5 standards. Consistent with the January 5 CASAC letter, it is proposed that alternative 24-hr and annual PM-2.5 standards will be examined alone and in combination with the current PM-10 standards.

The proposed PM health risk analyses are intended to provide additional insight about the extent to which at-risk populations may experience the specific health effects addressed in these analyses when various alternative standards are just attained. The staff believes that such information, when available, is useful to inform judgments about which alternative standards will protect public health with an adequate margin of safety. The staff recognizes that due to the many sources of uncertainty inherent in such analyses, any risk results should not be interpreted as precise measures of risk. Some of the major uncertainties are highlighted in the discussion below of the proposed structure and approach of the risk analysis, and also discussed in the section on

"Characterization of Uncertainty."

B. Structure of Risk Analysis

In order to estimate the change in health effects incidence corresponding to a given change in PM levels resulting from just attaining alternative standard scenarios and under "as is" conditions, the following three elements are required for a given health endpoint and chosen city:

- **Air Quality Information** which includes the following: (1) "as is" air quality data for both PM-10 and PM-2.5 from population-oriented monitors for that selected city, (2) estimates of background PM concentrations appropriate to that location, and (3) a method for adjusting the "as is" data to reflect patterns of air quality change estimated to occur when each city attains various alternative standards.

- **Concentration-Response Function(s)** which provide an estimate of the relationship between the health endpoint of interest and PM concentrations.

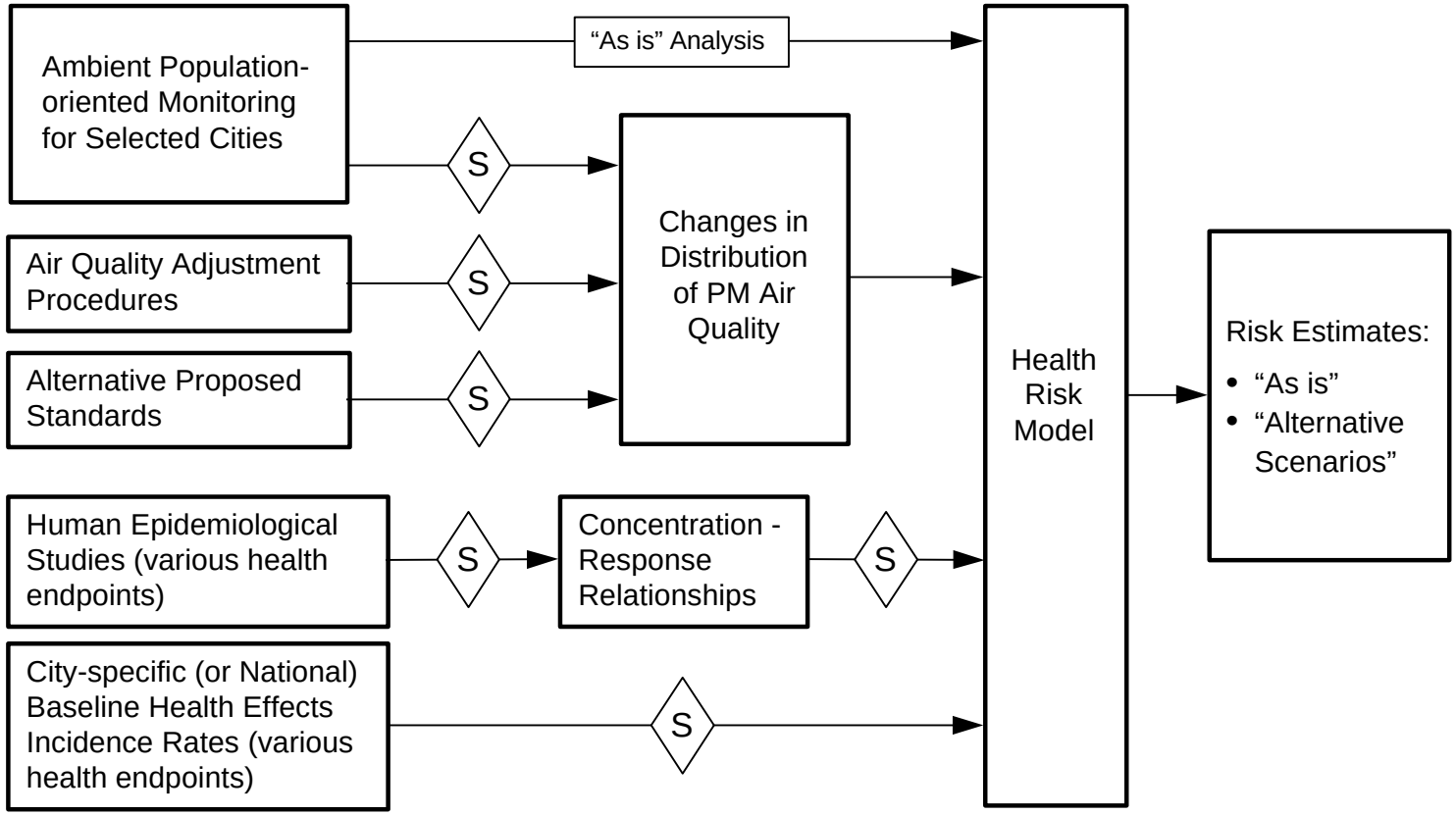
- **Baseline Health Effects Incidence Rates** which provide an estimate of the baseline health effects incidence or rate corresponding to "as is" PM levels.

Figure 1 provides a broad schematic of the role of these components in the risk analysis. The general health risk model which combines changes in PM air quality concentrations (Δx), the concentration-response relationships for a given health endpoint (reflected by β, the PM coefficient derived from epidemiology studies), and the baseline health effects incidence rate (y) for a given health endpoint is represented by equation 1:

Equation 1 $$\Delta y = y[e^{\beta \Delta x} - 1]$$

Estimates of risk (i.e. health effects incidences attributable to PM) are proposed to be quantified for PM concentrations above background except for those studies in which the range of observed PM concentrations did not go down to background (e.g., the prospective cohort mortality studies). For these studies effects will only be quantified down to the lowest concentrations observed in the study.

Figure 1 Major Components of Particulate Matter Health Risk Analysis



S = Sensitivity Analysis: Analysis of effects of alternative assumptions, procedures or data occurs at these points.

A more detailed discussion of the proposed methodology for the PM risk analysis is presented in "Proposed Methodology for PM Risk Analyses in Selected Cities" (Abt Associates, 1996). The sections below discuss key elements of the risk analysis where judgments must be made that will determine the nature and scope of the risk analysis.

C. Air Quality Considerations

1. Selection of Cities and Years to Include in Analysis

In examining the PM air quality monitoring database, several objectives were considered in selecting the cities for which the analysis of PM health risk is being proposed. These general objectives were:

- completeness of PM-10 and PM-2.5 air quality data (referring to both the frequency of monitoring and the number of monitoring sites),
- that the group of cities include cities where health effect epidemiological studies were conducted,
- that the group of cities include representatives of various PM aerosol mixes (e.g. Eastern cities, Western cities, areas with windblown dust, woodsmoke, valley locations, etc); as well as the range of PM concentrations observed in the U.S. (i.e., at least some sites with high pollution levels),
- recentness of air quality data .

Based on these objectives, the seven cities characterized in Table 1 are proposed as locations to assess the potential health risks of PM.

2. Estimating Air Quality Concentrations Under "As is" Air Quality

Two adjustments need to be made to the monitored "as is" air quality. First, it is proposed that average PM concentrations for each day will be calculated for all appropriate population-oriented PM monitors for each city. This is very similar to the procedures used in many of the epidemiology studies. Information will be provided as to how air quality varies among monitors.

Second, since the proposed presentation of results will report changes in the total annual incidence of health effects associated with short-term and long-term exposures for a particular year in each city, adjustments will be required to estimate the effects of PM on health in locations that have incomplete air quality data. While several of the selected cities have very complete PM monitoring data, none of the locations has 365 observations in a year. An adjustment will be made to normalize the health risk estimates so that all results will be expressed in terms of a complete year. Rather than extrapolate air quality values, risk estimates will be generated from all

Table 1. Cities proposed for risk analysis.

City	Year	% of days on which air quality data are available		Epidemiology function derived for that city?
		PM-10	PM-2.5	
Provo, UT	1994-95	94.5	44.7	Yes
St. Louis, MO metro area	1993	16.4	16.7	Yes
Spokane, WA**	1993-94	-***	-	Yes
Philadelphia, PA	1992-93	98.6	96.4	Yes*
Riverside, CA	1995	-	-	No
Washington, DC	1994	91.5	90.1	No
El Paso, TX	1986	79.2	44.7	No

* The epidemiology studies conducted in Philadelphia for mortality and hospital admissions used TSP as the indicator. While those studies agree qualitatively with studies conducted using PM-10 and PM-2.5 as the indicator, they will not be used for quantitative risk assessment.
**Some of the PM-10 and PM-2.5 air quality data for Spokane involve alternative monitoring methods. The effect of any differences resulting from the monitoring methods will be addressed in a sensitivity analysis.
***Statistics currently being generated.

Note: More detailed information about the air quality data in these cities is presented in Chapter 4 of Abt Associates, 1996.

the directly observed values, and then multiplied by a factor (365 days/ the number of days in a year for which direct observations were available) to generate an equivalent annual sum of health effects for that endpoint. In areas where monitoring frequency changes within the year of study (e.g., Riverside, CA) adjustments will be made separately to the seasons or periods with different frequency of monitoring. This method has the advantage of minimizing the inevitable uncertainty introduced by incomplete air quality data through use of the available air quality values, rather than interpolating values for the air quality data set.

3. Estimating Background Concentrations

Since health risks will only be calculated for concentrations exceeding estimated background levels, an estimate of background concentrations is needed to calculate risk at "as is" concentrations and for alternative standard scenarios. The background concentrations used for the Eastern and Western United States will draw upon the assessment of background concentrations contained in the February 1996 draft of the PM criteria document, together with CASAC's comments and recommendations.

4. Appropriate Adjustment Procedures to Model Attainment of Alternative Standards

To compare the "as is" PM health risk with the reductions in risk that occur under alternative standard scenarios, it is necessary to project what future PM air quality may be in an area "just attaining" these alternative standards. Any such projection introduces a significant additional degree of uncertainty into the risk analysis. However it is impossible to analyze potential effects of alternative standards on reducing health risk from PM without making some assumptions about the frequency distribution of 24-hr concentrations. This issue is important since many studies have associated 24-hr concentrations of PM with health effects, thus assumptions about the resultant distribution of 24-hr concentrations that would be observed after attainment of alternative standard scenarios may make a noticeable impact on the amount of risk reduction estimated.

As a starting assumption, it is proposed that "as is" PM levels be adjusted using a proportional change in air quality to just attain alternative standard scenarios. This "proportional rollback" of air quality values would calculate the amount of reduction required in an air quality statistic (e.g., annual mean or second daily max) in excess of background levels to meet the alternative standards, and reduce all air quality values that exceed the background concentration in the original set of "as is" concentrations by the same proportion as that required by the concentration or average that makes up the statistic itself. Sensitivity analyses will be provided that help bound the potential differences in risk reduction observed under different assumed air quality adjustment procedures (proportional rollbacks versus other possibilities). For example, one alternative could be a rollback in which extreme values were reduced more than annual mean concentrations, that is, in which peak concentrations are sizably reduced with little change to the rest of the distribution.

For those alternative standard scenarios in which the annual mean concentration is the controlling form of the standard, it is expected that variations in rollback procedure will have little or no impact on the health risk reduction observed. However, for those alternative standard scenarios in which the 24-hr standard is the controlling form of the standard, differences in patterns of air quality reduction may lead to differences in the estimated health risk reduction.

Preliminary analyses of PM-10 data from 1987-1994 have suggested that, at least in some locations, proportional rollbacks may reasonably model the pattern of PM-10 air quality

reduction observed. Further work characterizing the variability in rollback patterns observed among sites showing significant change in PM air quality will also be carried out and reported to inform the choices of air quality adjustment procedures used.

D. Concentration-Response Considerations

The health endpoints and studies to be included are drawn from Tables 13-3 to 13-5 of the February 1996 Draft of the Criteria Document. These tables list the studies evaluated as most appropriate for deriving quantitative estimates of health risk.

For the cities in which concentration-response functions that are included in Tables 13-3 to 13-5 have been reported, these specific functions will be used to estimate PM health risk. In addition, for endpoints in which several studies have been selected as appropriate, pooled analyses will be done using random effects models to combine the concentration-response relationships from these studies into "pooled functions." Sensitivity analyses will be performed to assess the impact of study selection on the "pooled function." (For instance, by comparing the risk estimates for endpoints for studies conducted in Provo, UT, with those obtained applying the pooled functions for those endpoints.) To assess the uncertainty inherent in the concentration-response relationships derived from multiple studies, Monte Carlo analysis also will be used. Repeated selection will be made in a two-step process: one of the studies will be selected from the set of studies used in the pooled analysis, and then a selection will be made of a concentration-response coefficient from the distribution of coefficients possible from that study. It is hoped this procedure will result in improved characterization of the degree of uncertainty contained in the concentration-response functions resulting from both within study and between study variability.

There will be discussion in the text about concerns that are more difficult to treat quantitatively, such as the potential differences in risk estimates that may result from: (1) differences in PM composition between the cities studied and those selected for the risk analysis, and (2) varying levels of associated copollutants in different cities. A quantitative sensitivity analysis will also compare the risk estimates resulting from use of single-pollutant PM concentration-response functions versus functions in which PM effects were assessed simultaneously with other pollutants (which is one possible approach to addressing the uncertainty concerning the role of copollutants).

Concentration-response functions will be used for PM-10 and PM-2.5 directly from the epidemiology studies that used these indicators. In addition, following suggestions made at the December CASAC meeting, we propose to generate equivalent PM-2.5 functions for a limited number of epidemiology studies that examined the effects of other indicators of fine PM (e.g., sulfates).

E. Baseline Health Effects Incidence Considerations

To accurately assess the impact of PM air quality on health risk in the selected cities, information on the incidence of health effects in each location is needed (this is because the studies report relative changes in health effects incidence as associated with PM-10). Where at all possible, the risk analysis proposes to use city-specific incidence rates for health endpoints. City-specific differences in mortality incidence are available from the National Center for Health Statistics, and this information shows wide differences between several of the selected cities.

For most if not all of the morbidity endpoints, however, city-specific incidence rates are difficult to obtain. Work is underway to see if city-specific rates for hospital admissions may be obtained, but for other morbidity endpoints, such as respiratory symptoms in children, incidence information aggregated at a higher level may be all that is available. The level of aggregation closest to city-specific will be used, but it is very possible that for some morbidity endpoints, only national-level incidence information will be available. A discussion will be presented of the rationale for the choice of incidence data used for each location. The lack of specific incidence data will increase uncertainty concerning the estimates of risk for specific cities.

One potential approach may be to adjust more aggregate incidence information by city-specific information for other endpoints, where available. For instance, national hospital incidence for various respiratory causes might be adjusted by the city-specific variations in mortality for those endpoints. Such a procedure would be weakest for endpoints in which a substantial proportion of the hospital admissions come from groups different from those that suffer mortality impacts, but might allow for a better estimate of city specific incidence than using national numbers alone (for example, a city with a higher rate of pneumonia mortality might be expected to have a higher than average rate of pneumonia hospital admissions). A quantitative comparison will be provided to help assess the accuracy of the proposed approach by comparing the incidence estimates for a selected city where extensive city-specific incidence information is available, using both the adjusted national or other aggregate incidence rates versus the actual city-specific incidence data for that city.

III. Characterization of Uncertainty

Any risk analysis and estimation of risk avoided under alternative standard scenarios will involve substantial uncertainties, and these difficulties are exacerbated for PM compared to the ozone risk assessment, given the diversity of composition in this generally defined pollutant. Among the major uncertainties in this risk analysis are:

- Concerns about the appropriate transferability of PM concentration-responses functions due to variations in PM composition across cities, the possible role of associated copollutants in influencing PM risk, and variations in the relation of total exposure to ambient monitoring in different locations. There is also the additional uncertainty concerning the tranferablility of health functions to future PM aerosol mixes.

- The air quality adjustment procedure that will be used to simulate just meeting alternative PM standards and how reductions may or may not differentially take place in fine and coarse particles.

- Use of baseline health effects incidence information that is not specific to the city in question. In addition, cities may have different proportions of members of sensitive subpopulations.

- Applying pooled concentration-response functions to represent the overall effect of particles on a particular health endpoint from studies in several locations.

- The impact of historical air quality on estimates of health risk from long-term PM exposures, as well as the duration of time that a reduction in particle concentrations must be maintained in a given location in order to experience the predicted reduction in health risk.

- The effect of normalizing the amounts of health risk experienced or reduced in different locations due to differences in the completeness of the air quality data sets.

- What is the most appropriate background concentrations for each location.

These and other uncertainties in this analysis are proposed to be handled in the following ways:

- Limitations and assumptions in the quantification process will be clearly stated and explained.

- Sensitivity analyses will be conducted to illustrate the effects of changing key default assumptions on the mean results of the assessment, and quantitative comparisons presented to inform other analytic choices.

- In the presentation of all health effects information, statistical uncertainty is quantified by presenting confidence intervals with all health effects results.

- A quantitative uncertainty analysis by Monte Carlo methods will be made to test the sensitivity and reveal the variance imbedded in pooled functions which combine several study results on a common endpoint.

IV. Presentation of Risk Results

A. "As Is" Risk Analysis for PM-10 and PM-2.5

Information concerning the risk from "as is" PM air quality is proposed to be presented in tabular and graphic form, including indications of statistical uncertainty (confidence intervals) for

health effects from both short-term and long-term exposure for the cities analyzed. The bulk of the information is proposed to be displayed in terms of estimates of annual health risk. For concentration-response relationships involving short-term exposures, this would represent the cumulative total impact of effects from the short-term PM concentrations across the year.

Several options for presenting information exist, from curves of cumulative risk, graphs of the distribution of risk across different parts of the air quality distribution, and Tables that allow the summary of many results in a compact format. Examples of these will be provided at the February 29th meeting.

B. Alternative Standards Analysis

It is proposed that most of the information reporting results from alternative standards analyses be provided in tables. These tables would show estimated risk reductions in each city for a variety of endpoints, including measures of uncertainty, associated with reductions in PM concentrations to attain several alternative scenarios. The alternative scenarios to be analyzed are envisioned to involve combinations of alternative 24-hr and annual PM-2.5 standards and the current PM-10 standards. The results will include indications of the percentage reduction in relative risk observed between those scenarios versus the "as is" case. A table comparing results across cities also is planned, at least for some endpoints.

Since several of the cities attain the current PM-10 standards, the "as is" analysis represents risk that can be associated even with attainment of the current standards. For two of the cities, the "as is" case exceeds current standards (El Paso in 1986 and Riverside in 1995). For these cities, any comparisons to alternative standard scenarios will be made based on a modified "as is" air quality data set that will be adjusted to attain the current standards. This will avoid ascribing excessive amounts of risk reduction to the alternative standards. In addition, some of the cities have PM-2.5 concentrations within the staff's recommended range for alternative PM-2.5 standards. For those cities we do not propose to "roll up" air quality to estimate how air quality theoretically might worsen in these locations under alternative scenarios.

C. Sensitivity Analyses

Table 2 indicates the sensitivity analyses and quantitative comparisons proposed for this analysis.

Table 2. Planned Sensitivity Analyses and Quantitative Comparisons

Component of the Risk Analysis	Sensitivity Analysis or Comparison
Air Quality	Comparison will be made of different methods of aggregating, interpolating, and adjusting air quality monitoring information to account for different frequency of sampling among monitors and across locations
Air Quality	A sensitivity analyses of the effect of different rollback assumptions (i.e. alternative air quality adjustment procedures) on the risk reduction obtained by alternative 24-hr and annual standards
Baseline Incidence	A comparison of using more aggregate incidence data (national, state, etc) versus city-specific information in the city with the best local incidence data
Conc-Response	A comparison or sensitivity analysis of methods of combining averaging times of from 1 to 5 days in the short-term mortality studies
Conc-Response	A sensitivity analysis comparing the risks calculated by using concentration-response functions derived for the specific city in question versus pooled functions for endpoints
Conc-Response	A sensitivity analysis or comparison of the effects of including or excluding individual studies from pooled functions to show the sensitivity of the function to inclusion of specific studies
Conc-Response	A sensitivity analysis using concentration-response functions for PM from multi-pollutant regressions with copollutants versus single pollutant regressions
Conc-Response	A comparison or sensitivity analysis of the impact on risk results for long-term mortality concentration-response functions due to different assumptions about the role of historical air quality concentrations in contributing to the reported effects.
Conc-Response	A sensitivity analysis assuming alternative minimum concentration levels for the occurrence of PM health effects at concentrations above those for background
Conc-Response	Monte Carlo Analyses will be presented to illustrate the total variance of the risk estimates due to alternative concentration-response relationships.